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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/893,339	ROSENTHAL ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-84* is/are pending in the application.

4a) Of the above claim(s) *59-62,64,65 and 72-84* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19,24,27-34,47-50,52-58,63 and 66-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendment filed 08 December 2003 has been entered in part. Newly submitted claims 59-62, 64, 65, 72-84 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicants elected species G-CSF (growth factor), hydroxypropyl methylcellulose (second biocompatible polymer), polyoxypropylene (first biocompatible polymer). Please see Elections, 22 October 2002 and 24 February 2003.

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits.

Accordingly, claims 59-62, 64, 65, 72-84 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 1-19, 24, 27-34, 47-50, 52-58, 63, 66-71 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The rejection of claims 29 and 31 under 35 USC 112, second paragraph as set forth at page 3 of the previous Office Action (04 June 2003) is *withdrawn* in view of the amendment (08 December 2003).

The rejection of claims 1, 4-13, 15-19, 24, 27-34, 36, 49-52 under 35 U.S.C. 103(a) as being unpatentable over Stratton *et al.*, US Patent 5,861,174 in view of Gentz *et al.*, US Patent No. 6,238,888 B1 as set forth at page 3-5 of the previous Office Action (04 June 2003) is *withdrawn*.

The rejection of claims 27-32, 36 and 47 under 35 U.S.C. 103(a) as being unpatentable over Stratton *et al.*, US Patent 5,861,174 and Gentz *et al.*, US Patent No. 6,238,888 B1 as applied to claims 1, 4-13, 15-19, 24, 27-34, 36, 49-52 and in further view of Roos *et al.*, US Patent No. 5,840,338 as set forth at page 5-7 of the previous Office Action (04 June 2003) is *withdrawn*.

The rejection of claims 2 and 3 under 35 U.S.C. 103(a) as being unpatentable over Stratton *et al.*, US Patent 5,861,174 and Gentz *et al.*, US Patent No. 6,238,888 B1 as applied to claims 1, 4-13, 15-19, 24, 27-34, 36, 49-52 and in further view of Chan *et al.*, US Patent No. 5,702,717 as set forth at page 7-8 of the previous Office Action (04 June 2003) is *withdrawn*.

Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19, 24, 27-34, 47-50, 52-58, 63, 66-71 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a hematopoietic growth factor delivery composition, the composition comprising G-CSF capable of stimulating hematopoietic cell activity when administered to a mammalian host;

a first biocompatible polymer, **wherein a first biocompatible polymer is polyoxyethylene-polyoxypropylene (POE-POP)** and a liquid vehicle in which the first biocompatible polymer is at least partially soluble at some temperature, the first biocompatible polymer interacting with the liquid vehicle to impart reverse thermal viscosity behavior to the composition over at least some temperature range, so that the composition is in a lower-viscosity form when the temperature of the composition is at a first temperature within the range and the composition is in a higher-viscosity form when the temperature is at second temperature within the range that is higher than the first temperature, and

a second biocompatible polymer, **wherein a second biocompatible polymer is hydroxypropylmethylcellulose (HPMC)**, being a protective colloid that inhibits the dissolution into aqueous liquids of the first biocompatible polymer at least when the composition is in the higher-viscosity form wherein the liquid vehicle comprises from 60 weight percent to 96 weight percent of the composition, the first biocompatible polymer comprises from 5 weight percent to 33 weight percent of the composition, and the second biocompatible polymer comprises from 0.1 weight percent to 5 weight percent of the composition.

does not reasonably provide enablement for

a hematopoietic growth factor delivery composition comprising any type of hematopoietic growth factor and any type of biocompatible polymer.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The scope of patent protection sought by Applicant as defined by the claims fails to bear a reasonable correlation with the scope of enabling disclosure set forth in the specification because the specification only teaches hematopoietic cell activity upon administration of a hematopoietic growth factor delivery composition comprising *specific growth factors, polyoxyethylene-polyoxypropylene (POE-POP) and hydroxypropyl-methylcellulose (HPMC).* The instant specification fails to teach that any type of hematopoietic growth factor or any type of polymer could be used in the instant delivery system. Hematopoietic growth factors comprise different structures (monomers, disulfide-linked dimers, diverse molecular weights) and it is in no way predictable that the any biocompatible polymer employed would not alter the half-life, stability, delivery and/or the functional properties of the growth factor. The instant claims encompass all types of hematopoietic growth factors and any sort of biocompatible polymer. The specification teaches hematopoietic activity with a delivery composition comprising a specific combination of components formulated in an exacting manner. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth.

Due to the large quantity of experimentation necessary to generate a hematopoietic growth factor delivery composition comprising any type of hematopoietic growth factor and biocompatible polymer and screen same for activity, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, and the breadth of the claims which fail to recite any limitations regarding suitable growth factors and biocompatible polymers, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RMD
3/3/04

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